

AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

In the Claims

Claims 1-35 (cancelled)

36. (currently amended) A seed, for implantation into a subject, wherein the seed is a combination product comprising

- a) a biocompatible carrier,
- b) one or more therapeutic components,
- c) an imaging, radiopaque, or other diagnostic marker, and
- d) one or more structures to maintain location or orientation of the seed selected

from the group consisting of one or more biodegradable structures effective to prevent migration upon implantation of the seed in tissue, one or more biodegradable structures effective to maintain orientation in tissue, and one or more compliant setal or hair structures which impart adhesive properties upon implantation into a target tissue,

wherein the one or more structures effective to prevent migration or maintain orientation in tissue ~~are selected from the group consisting of~~ comprise studs, knobs, ribs, fins, grapple shaped anchors, wings, stabilizers, bristles, rings, bands, hooks, ~~knots, twists, braids, coils, and~~ or combinations thereof,

wherein the one or more structures prevents migration of the seed for a period of time from about 10 minutes to about three years,

AMENDMENT AND RESPONSE TO OFFICE ACTION

wherein the seed has a size and shape suitable for passing through the bore of a needle or catheter having an interior diameter of less than about 2.7 mm (10 gauge).

37. (previously presented) The seed of claim 36 wherein the seed is shaped into a cylinder or rod having a diameter of between about 0.8 to 3 mm and a length of up to 40 mm.

38. (previously presented) The seed of claim 36 wherein the biodegradable structures are comprised of polymeric substances.

39. (previously presented) The seed of claim 36 wherein the biodegradable structures are comprised of non-polymeric or inorganic substances.

40. (previously presented) The seed of claim 36 wherein more than one seed is formed as a continuous chain or array of seeds.

41. (previously presented) The seed of claim 40 wherein the chain or continuous array includes spacer material.

42. (previously presented) The seed of claim 40 wherein one or more seeds are elongated into strands to form a continuous chain or array of seeds.

43. (previously presented) The seed of claim 41 wherein the seeds and spacers in the chain or continuous array are indistinguishably linked.

44. (previously presented) The seed of claim 41 wherein the color, texture, diameter, hardness, or shape of the spacers is used for identification and demarcation.

AMENDMENT AND RESPONSE TO OFFICE ACTION

45. (previously presented) The seed of claim 40 wherein the chain or continuous array comprises indiscrete seeds, is flaccid, rigid, flexible, spring-shaped, coiled, spiral-shaped, springy, bent, latticed, knotted, interconnected, linked, or fused.

46. (currently amended) The seed of claim 41 wherein spacers are located at varying distances from one another, separated by one, two, three, four, five or more seeds or wherein the seeds are located at varying distances from one another, separated by one, two, three, four, five, or more spacers.

47. (canceled)

48. (previously presented) The seed of claim 36 wherein the structures to maintain location or orientation comprise a smart polymer, a shape memory polymer, or other substrate to achieve configuration modification.

49. (previously presented) The seed of claim 36 wherein the biocompatible carrier is elastic.

50. (previously presented) The seed of claim 36 wherein one or more of the therapeutic components is radioactive.

51. (previously presented) The seed of claim 36 wherein one or more of the therapeutic components is non-radioactive.

52. (previously presented) The seed of claim 36 wherein the imaging, radiopaque, or diagnostic marker is the biocompatible carrier.

AMENDMENT AND RESPONSE TO OFFICE ACTION

53. (currently amended) The seed of claim [[36]] 50 further comprising a means of tracing the radioactive contents comprising the radioactive component.

54. (previously presented) The seed of claim 53 wherein the tracer is fluorescent, luminescent, colored, pigmented, dyed, tagged, or quantum dots.

55. (previously presented) The seed of claim 36 wherein one or more of the components comprises a biodegradable magnetic polymer suitable for heating in a magnetic field.

56. (previously presented) The seed of claim 42, wherein two or more strands are combined to form a knot, twist, coil, or combinations thereof.

57. (previously presented) The seed of claim 40, wherein the chain of seeds is configured into a knot, twist, coil, or combinations thereof.

58. (currently amended) The seed of claim 36, wherein the one or more structures [[to]] that maintain location or orientation of the seed or impart adhesive properties to the seed, cover at least a portion of the seed.

59. (previously presented) The seed of claim 42, wherein the one or more structures to maintain location or orientation of the seed or impart adhesive properties to the seed cover at least a portion of the seed.

60. (currently amended) A seed, for implantation into a subject, wherein the seed is a combination product comprising

a) a biocompatible metallic carrier,

AMENDMENT AND RESPONSE TO OFFICE ACTION

b) one or more therapeutic components,

c) an imaging, radiopaque, or other diagnostic marker, and

d) one or more biodegradable structures to maintain location or orientation of the seed ~~selected from the group consisting of one or more biodegradable structures effective to prevent migration of the seed upon implantation in tissue, one or more biodegradable structures effective to maintain orientation in tissue, and one or more compliant setal or hair structures which impart adhesive properties,~~

wherein the one or more biodegradable structures effective to prevent migration or maintain orientation in tissue comprise one or more bands, ~~and~~ one or more ribs or wings, and combinations thereof

wherein the seed has a size and shape suitable for passing through the bore of a needle or catheter having an interior diameter of less than about 2.7 mm (10 gauge).

61. (currently amended) The seed of claim 36, wherein the seed is administered using an apparatus for implanting seeds at ~~regularly spaced~~ designated intervals in tissue.

62. (currently amended) The seed of claim 42, wherein the seed is administered using an apparatus for implanting seeds at ~~regularly spaced~~ designated intervals in tissue.

63. (currently amended) The seed of claim 60, wherein the seed is administered using an apparatus for implanting seeds at ~~regularly spaced~~ designated intervals in tissue.

64. (previously presented) The seed of claim 61, wherein the seed is in a magazine or cartridge.

AMENDMENT AND RESPONSE TO OFFICE ACTION

65. (previously presented) The seed of claim 62, wherein the seed is in a magazine or cartridge.

66. (previously presented) The seed of claim 63, wherein the seed is in a magazine or cartridge.

67. (currently amended) The seed of claim 36, wherein the one or more structures prevents migration or maintains orientation of the seed for a period of time of at least about one hour.

68. (currently amended) The seed of claim 36, wherein the one or more structures prevents migration or maintains orientation of the seed for a period of time of at least about three weeks.

69. (currently amended) The seed of claim 36, wherein the one or more structures prevents migration or maintains orientation of the seed for a period of time of at least about three months.

70. (currently amended) The seed of claim 36, wherein the one or more structures prevents migration or maintains orientation of the seed for a period of time of at least about six months.

71. (previously presented) The seed of claim 36, wherein the one or more therapeutic components; imaging, radiopaque, or other diagnostic marker; or combinations thereof are within the one or more biodegradable structures.

AMENDMENT AND RESPONSE TO OFFICE ACTION

72. (previously presented) The seed of claim 36, wherein the one or more biodegradable structures comprise one or more ribs or wings..

73. (previously presented) The seed of claim 60, wherein the one or more biodegradable structures comprise one or more ribs or wings.

74. (previously presented) The seed of claim 50, wherein the seed provides substantially uniform dosimetry.

75. (previously presented) The seed of claim 36, wherein the one or more biodegradable structures are in the form of a coating or sleeve that encapsulates at least a portion of the seed.

76. (previously presented) The seed of claim 60, wherein the one or more biodegradable structures are in the form of a coating or sleeve that encapsulates at least a portion of the seed.

77. (previously presented) The seed of claim 72, wherein the one or more biodegradable structures are in the form of a coating or sleeve that encapsulates at least a portion of the seed.

78. (previously presented) The seed of claim 73, wherein the one or more biodegradable structures are in the form of a coating or sleeve that encapsulates at least a portion of the seed.

79. (previously presented) The seed of claim 36, wherein the seed comprises radioactive and non-radioactive therapeutic components.

AMENDMENT AND RESPONSE TO OFFICE ACTION

80. (new) A therapeutic implant for use in brachytherapy, comprising
- a single radioactive seed that includes radioactive material contained within a metallic housing; and
- a polymeric material molded to completely encapsulate the metallic housing of the single radioactive seed;
- wherein an outer surface of the encapsulating polymeric material defines one or more ribs having a substantially squared profile formed by a stepped portion extending between a pair of sidewalls to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation; and
- wherein a thickness of the encapsulating polymeric material varies such that the thickness is greater where there is one of the one or more ribs than where there is not a rib.
81. (new) The implant of claim 80, wherein the one or more ribs are made from the polymeric material that encapsulates the metallic material of the single radioactive seed.
82. (new) The implant of claim 81, wherein the polymeric material is bioabsorbable.
83. (new) The implant of claim 80, wherein the one or more ribs are defined by a shape of a mold that is used to encapsulate the seed.
84. (new) The implant of claim 80, wherein the one or more ribs form one or more rings or a helix about the radial circumference of the metallic housing of the radioactive seed.

AMENDMENT AND RESPONSE TO OFFICE ACTION

85. (new) The implant of claim 80, wherein the thickness of the encapsulating polymeric material that encapsulates the metallic housing of the single radioactive seed is at least 0.002 inches.

86. (new) The implant of claim 80, wherein at least one of the one or more ribs extends at least 0.002 inches beyond portions of the encapsulating polymeric material where there is not a rib.

87. (new) The implant of claim 80, wherein the metallic housing of the single radioactive seed includes first and second longitudinal ends, and wherein the one or more ribs are located between the longitudinal ends of the metallic housing of the single radioactive seed.

88. (new) The implant of claim 80, wherein the metallic housing of the single radioactive seed has a substantially smooth outer surface, without any protrusions, that is completely encapsulated by the polymeric material.

89. (new) The implant of claim 80, wherein the polymeric material is bioadhesive.

90. (new) The implant of claim 80, wherein the biomaterial is bio-adherent.

91. (new) A therapeutic implant for use in brachytherapy, comprising
a single radioactive seed that includes radioactive material contained within a
metallic housing having a substantially smooth outer surface; and
a polymeric material molded to completely encapsulate the metallic housing of
the single radioactive seed;

AMENDMENT AND RESPONSE TO OFFICE ACTION

wherein an outer surface of the encapsulating polymeric material includes a plurality of ribs having a substantially squared profile formed by a stepped portion extending between a pair of sidewalls to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation; and

wherein the ribs are defined by variations in a thickness of the encapsulating polymeric material, not by an outer surface of the underlying metallic housing.

92. (new) The implant of claim 91, wherein the polymeric material is bioadhesive.

93. (new) The implant of claim 91, wherein the biomaterial is bio-adherent.

94. (new) The implant of claim 91, wherein a thickness of the encapsulating polymeric material varies such that the thickness is greater where there is a rib than where there is not a rib.

95. (new) An anchor mechanism to reduce a tendency for a structure to migrate or rotate after implantation of the structure into a patient, where the structure is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, the anchor mechanism comprising:

a sleeve to fit around the structure,

the sleeve having a bore that extends an entire longitudinal length of the sleeve, and through which the structure fits, such that a portion of the structure extends out from each longitudinal end of the sleeve; and

AMENDMENT AND RESPONSE TO OFFICE ACTION

one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions to receive surrounding patient tissue upon implantation of the structure into a patient, to thereby reduce a tendency for the structure to migrate and rotate after implantation,

wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion.

96. (new) A therapeutic implant, for use in brachytherapy , comprising:

a structure that is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, and an anchor mechanism comprising:

a sleeve to fit around the structure,

the sleeve having a bore that extends an entire longitudinal length of the sleeve, and through which the structure fits, such that a portion of the structure extends out from each longitudinal end of the sleeve; and

one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the

AMENDMENT AND RESPONSE TO OFFICE ACTION

protrusions to receive surrounding patient tissue upon implantation of the structure into a patient, to thereby reduce a tendency for the structure to migrate and rotate after implantation,

wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion.

97. (new) A method for using a therapeutic implant in brachytherapy comprising:

providing a structure that is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, and an anchor mechanism comprising:

fitting a sleeve to fit around the structure such that a portion of the structure extends out from each longitudinal end of the sleeve; wherein the sleeve includes one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions,

loading the structure, with the sleeve around the structure, into a hollow needle; and

using the hollow needle to implant the structure, with the sleeve around the structure, into patient tissue;

wherein the patient tissue is caught in at the at least one space upon implantation of the structure, with the sleeve around the structure, to thereby reduce a tendency for the structure to migrate and rotate at implantation; and

U.S.S.N. 10/665,793

Filed: September 19, 2003

AMENDMENT AND RESPONSE TO OFFICE ACTION

wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion.